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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,723	03/20/2001	James A. Langham JR.	BMA-008	2606
21323	7590	07/30/2004	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110			SOOHOO, TONY GLEN	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 07/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,723

Applicant(s)

LAUGHARN ET AL.

Examiner

Tony G Soohoo

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-40, 43, 45, 47, 51, 54, 63, 68, 77, 113-115, 118, 120, 122, 126, 129, 137, 142 and 151-153 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 38-40,43,45,47,51,54,63,68,77,113-115,118,120,122,126,129,137,142 and 151-153.

Office Action Summary

~~Continuation Sheet~~

* Page 1 con'td

TBS

Election/Restrictions

1. Pending Elected claims are 38-40, 43, 45, 47, 51, 54, 63, 68, 77, 113-115, 118, 120, 122, 126, 129, 137, 142, and 151-153.

Priority

2. The typographic error has occurred in the request for priority under 119(e), is acknowledged. The correct the application number of the request to a priority is 60/263,838 as indicated in the papers filed Feb 12, 2002.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 38, 39, 40, 43, 47, 63, 68, 113, 114, 115, 118, 122, 137, 142, are rejected under 35 U.S.C. 102(b) as being anticipated by Jacke et al 2950725.

The scope of the claims are so broad that the device of the Jacke reference anticipates the claim limitations.

With regards to the apparatus and method, the Jacke reference and its operation discloses an ultrasonic acoustic source 14, 32-36 with a focused field for directing it to a nucleation feature (in this case the crevices between the wires of container 18) which thereby inherently causes nucleation cavitation (including bubbles) which then imparts motion to the fluid adjacent to the wires of the basket 18 of a fluid such that upon a release of a bubble motion is further imparted to the fluid next to the body 21 to be cleaned and the fluid next to the body to be cleaned in 21 is moved about; a controller to control the acoustic source, see figure 7 (claims 38, 39); and the further adaptation whereby the acoustic field is selectively directed to a nucleation feature at the basket wires with gaps and crevices between the wires and has (claim 47, 118) a focused arrangement due to the concave curvature of 14 (claim 142) and the provision of a movable means 17 for relative positioning (claim 40, 68,) of the gaps and crevices of the wire basket active site having inherently a 1st surface and "a nucleation feature" on the surface (claim 43) in particular in the form gaps, crevices and have defects in the wires forming the basket (claim 47, 118) in which formed bubbles may attach upon the gaps, cracks, crevices between the wires and the bubbles may release or implode thereby inherently displacing fluid and causing agitation and mixing of the fluid that is proximate to the active site of the gaps and crevices of the wire basket (claim 63, 137).

The inherent, formation of nucleation cavitation produced bubbles caused by ultrasound and the interaction of such nucleated bubbles upon surfaces having scratches, cracks, and very small imperfections is deemed old and well known in the art. This interaction is as deemed as an inherent physical fact in the acoustic art, as

Art Unit: 1723

evidenced by prior art references Bran 5,037,481, column 1, lines 28-31. and Alliger Re. 31,779, column 5, lines 55-57, and column 6, lines 14-18.

It is noted that the argument of applicant's remarks on page 8, 2nd paragraph, that "[the Jacke reference] does not teach or suggest directing an acoustic beam at the nucleation site proximate to an active site such that motion is imparted to a constituent in the fluid proximate to said active site is non-persuasive.

It is noted that the claims do not require an acoustic beam. Furthermore the scope of the terms "nucleation site proximate to an active site" and "motion imparted to a constituent in the fluid proximate to the active site" is so broad and vague in scope that it encompasses a structure of a gap between the wire baskets fulfilling the term nucleation site, the active site as the walls of the basket itself, and the fluid within the basket volume as the fluid proximate the active site.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 38-40, 43, 45, 47, 51, 54, 63, 68, 77, 113-115, 118, 120, 122, 126, 129, 137, 142, and 151-153 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wohlstadter et al 6413783.

Art Unit: 1723

The Wohlstadter reference teaches the provision and method of providing a small chamber 11 holding a fluid 12 whereby there is a notch, in the cavity 17 located above 15 whereby a sonicating device 16, 26 (acoustic source) is controlled (column 10, line 25-26), directed, and selected to be focused into the chamber 17, the sonication is of the frequency range which may produce mixing, see column 5, lines 51-66 and desires the promotion of mixing (column 10, lines 30-35). It is also noted that the may be used in the medical field, column 1, line 65-67.

The Wohlstadter discloses all of the recited subject matter as defined within the scope of the claims with the exception of the acoustic field being directed to a "nucleation feature" of a pit, crevice, defect, scratch, groove or ridge in the surface of the chamber 17. Although Wohlstadter shows a notch section, it is may be argued that the feature of the notch may not satisfy a "nucleation feature". Accordingly, it is noted that the surface of 17 is a manufactured product and the surfaces are subject to manufacture errors and tolerances, whereby almost all manufactured materials, at least in the microscopic level, have small scratches, pits, grooves, or ridges, whereas if a device is manufactured and operated such that the surface is so polished to a degree that there are no small scratches, pits, grooves, or ridges, the cost would be prohibitive in manufacturing the product in a cost-effective manner.

Accordingly, it is deemed that it would have been obvious to one of ordinary skill in the art to manufacture the inside surfaces of 17 so that the tolerance of the smoothness of the surface would have small scratches, pits, grooves, or ridges, thereby the manufacturing cost would be not prohibitive and the product in a cost-effective

Art Unit: 1723

manner. With regards to the method claim, the use of such a product would satisfy the recited claimed limitations whereby the small scratches, pits, grooves, or ridges, would be affected by the sonication device thereby inherently producing a mixing effect.

With regards to the feature of the use of a microchamber, and the volume size of 0.1 pl and 10ml, of the chamber, the Wohlstadter discloses all of the recited subject matter as defined within the scope of the claims with the exception of the use of a "cell", whereby a microchamber and the volume as recited in the claims are merely directed to the size of the volume of the chamber, and whereby the Wohlstadter reference is used in the medical field whereby small samples are commonly used, it would have been an obvious matter of design choice to optimize the size of the chamber and the volume of the chamber to handle micro size volumes of fluid for the sake of using less sample fluid for each processing by the method and device, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

With regards to the use of a biological fluid, it is noted that Wohlstadter et al teaches the use of the device in the medical field, column 1, lines 20-65, thus it is deemed that it would have been obvious to one of ordinary skill in the art to use a biological fluid in the device and process of operation of the device by Wohlstadter so that it provides a useful manner to mix fluids in the medical field.

With regards to applicants arguments on page 9 of the arguments of 10/17/2003 that the Wohlstadter reference that Wohlstadter scatters acoustic energy into a mixing

chamber for mixing and are not selectively directed. It is noted that the scope of the claim language is broad and does not distinguish a difference of a focusing of acoustic energy into a "site" of a chamber having surface imperfections which would produce cavitation of that of Wohlstadter. There is no distinguishing recitation in the claim to exclude the arrangement of the "selective directing" is limited to only focusing acoustic energy to a single a focal point of a crevice of a surface, as seen in applicant's figures 9, 12, 13, 18. In fact, the claim does not even limit that the active site is a surface nor limit that the nucleation site is upon the active site. Whereas the as the claims are so broad and vague, the claims are readable and are anticipated upon the references.

Response to Arguments

7. Applicant's arguments filed 10/17/2003 have been fully considered but they are not persuasive.

8. As also set forth in a prior discussion in the response of October 17, 2003, Applicant alleges that the Jackie reference does not teach or suggest "selectively directing an acoustic field to an at least one nucleation feature located proximate to an active site to impart motion to a constituent in the fluid proximate the active site to impart a motion to a constituent in the fluid proximate to said active site."

9. In response the operation and structural elements as provided by the Jackie and the constituent elements provided during operation provides such a feature, see discussion addressed above in paragraphs 4 and 6.

Conclusion

10. This is a CONTINUATION of applicant's earlier instant Application. All claims are drawn to the same invention claimed in the earlier application and could have been

Art Unit: 1723

finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

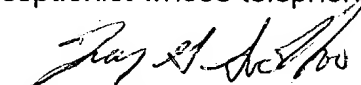
11. The cited prior art made of record made previously, and not relied upon, is considered pertinent to applicant's disclosure as further examples of a selective directing of an acoustic field upward toward the active site of a microchamber whereby the curvature of the chamber or surface defects in the tube may produce a nucleation feature.

12. Previously cited prior art made of record and not relied upon is considered pertinent to applicant's disclosure as support for the inherent formation of nucleation upon nucleation features. Bran 5037481 and Alliger Re.31779 is cited as background support of known physical effects of sonication upon bubble formation and nucleation features. The following disclose sonication devices: Miles et al 6100084, Brown et al 3876890, Jones 2855526, Bjornson et al 6284113, Evensen et al 5890802, Vota 4488816, Yasuda et al 6244738, Anderson et al 3396286, Williams 2565159, O'Neill 3066686, Nesh 3194640, Camp 2864592, Honda 4834124, Haller et al 6010316, Dion et al 6361747.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tony G Soohoo whose telephone number is (571) 272

Art Unit: 1723

1147. The examiner can normally be reached on 7:00 AM - 5:00 PM, Tues. - Fri.. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1700.


Tony G Soohoo
Primary Examiner
Art Unit 1723

TONY G. SOOHOO
PRIMARY EXAMINER

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